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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,362	09/16/2003	Roger Massengale	IFLOW.149A	1650

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/19/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com
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Office Action Summary

Application No.

10/663,362

Applicant(s)

MASSENGALE ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply:

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-24 is/are pending in the application.
- 4a) Of the above claim(s) 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 2/08/2007 in which claim 1 was amended to incorporate dependant claim 3, and claim 3 was cancelled. Currently claims 1-2, and 4-24 are pending for examination with claims 17-24 withdrawn from a previous election restriction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7-9 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed, Jr. (5,827,530). Reed, Jr. discloses a fillable patch for dermal or transdermal delivery.

Regarding claims 1, 3-5, 7-9 and 12-14, Reed, Jr. discloses a fluid medication delivery device comprising a fluid impermeable layers (26, 14), a fluid semi-permeable layer (16, 28) wherein the two layers define a fluid reservoir space in between, a fluid inlet (32,34) comprising a valve that allows for fluid entry wherein the device is capable of perfusing liquid through the permeable layers when pressure is imparted on the fluid (col 3 ln 34-67, col 4 ln 1-44) (Figure 2). Additionally, the valve is configured to allow fluid to enter the reservoir but prevent fluid from exiting the fluid reservoir (col 4, ln 1-10) wherein the fluid reservoir comprises walls that are all heat sealed together (18, 20, 23)

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and also comprises a segmenting element (40) that defines a separate space in the reservoir (Figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 15-16 are rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr. in view of Meconi et al. (5,770,220). Reed, Jr. meets the claim limitations as described above except for the materials disclosed and a semi permeable layer that is external to the fluid pouch.

However, Meconi et al. teaches an active substance-containing patch.

Regarding claims 6 and 15-16, Meconi et al. teaches a fluid delivery device that discloses a layer material to is selected from polyethylene, polysulfone, polyethersulfone, polyvinylidene difluoride, polycarbonate, nylon, HD polyethylene, and

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PTFE (col 2 ln 27-68, col 3 ln 1-46) wherein the semi permeable layer is located outside the fluid pouch (Figures 1-2).

At the time of the invention, it would have been obvious to use the semi permeable layer of Meconi et al. with the system of Reed, Jr. because the specific materials and structure allows for controlled fluid delivery by varying the material properties for diffusion. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Meconi et al.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Reed, Jr. of the materials as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claim Rejections - 35 USC § 103

Claims 2 and 10-11 are rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr.

Reed, Jr. discloses a fillable patch for dermal or transdermal delivery.

Regarding claims 2 and 10-11, Reed, Jr. discloses the claimed invention except for specific material dimensions (0.25 microns-0.254 mm) and pore sizes (0.25 micron) of the semi permeable layer and adjacent walls. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the semi

permeable layer and walls with the pore sizes and dimensions as claimed by Applicant, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 2/08/2007 have been fully considered but they are not persuasive. Applicant's representative asserts that the Reed, Jr. reference does not disclose a "one-way valve configured to permit fluid to enter said fluid reservoir and preventing fluid from exiting said fluid reservoir through said fluid inlet" and that the Reed, Jr. further does not disclose "a fluid impermeable pouch having first and second opposing walls, said first and said second wall defining a space therebetween.

Examiner disagrees with Applicant's representative's narrow interpretation of the reference and the conversely claimed subject material. Reed, Jr. clearly discloses the valve disclosed (col 4, ln 1-10) that is configured to permit fluid flow and seal as claimed by Applicant, and is *configured* to act as the one-way valve disclosed; additionally any valve can fail under the appropriate valve back pressure, as a one-way check valve, under enough back pressure this valve will also leak. Reed, Jr. additionally disclose the impermeable pouch as claimed, the two layers of (22, 16) or (22, 14) are composed of a fluid impermeable layer 22 and a diffusion layer which is only semi-permeable, Applicant has not claimed the layers are entirely or completely impermeable, the porous film layer (16) meets Applicant's limitation and with the addition of the initial release liner (14) the entire system becomes completely impermeable. Additionally, if Applicant

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contends that Applicant's claimed invention is completely or entirely impermeable. Examiner questions this argument in that the layer (32) with holes (35) shown in Figure 7 is not in fact impermeable to fluid. Therefore, examiner has fully considered applicant's arguments but they are not persuasive. It is examiner's position that given a careful reading, the claims do not distinguish over the prior art of record. The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

4/12/02


NICK LUCCHESI
SENIOR PATENT EXAMINER
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Christopher D. Koharski
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